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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,814	12/22/2000	Rene C. Gaudreault	PA-153	9015

7590

08/14/2002

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Alexandria, VA 22314

EXAMINER

VOLLANO, JEAN F

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 08/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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25545 7590 01/02/2002

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Office Action Summary

Application N

09/741,814

Applicant(s)

GAUDREAU ET AL.

Examiner

Jean F. Vollano

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1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 5-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The election filed 11/26/2001 has been entered. Applicants have elected Group II, claim 4 drawn to a method of selectively targeting protein receptors found with a compound of formula

1. Claims 1-3 and 5-7 are withdrawn from consideration as being drawn to a non elected invention.

2. There has been no traversal of the restriction. The restriction is proper and MADE FINAL.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 4 is not found in the specification and as such the specification lacks antecedent basis for the claimed subject matter. However since the claim is an original claim and the claims as filed in the original specification are part of the disclosure, therefore if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter.

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Claim Rejections - 35 USC § 112

3. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The elements of what constitutes selectively targeting a protein using formula 1 as relates to the testing parameters to be used and what constitutes a responsiveness of the molecule which are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

There appears to be no portion of the specification which defines what constitutes components of the method steps that are being claimed. There is no guidance in the specification of what the elements are to be used in the method being claimed. How should the testing be performed? How does one isolate effect and responsiveness ? What does one do with the knowledge gained from isolating the effect and responsiveness to determine what is a target protein receptor? One could not use the method as given in the specification to selectively target proteins.

4. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation of “molecule of formula I, prodrugs thereof”.

A prodrug is usually a protected group which cleaves after the drug is in the body. For example and ester can be a prodrug of an acid which hydrolyzes to the acid in the body or cell culture.

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However in this instance there is a formula which has alkyl groups, a halogen on a carbon chain and two nitrogens as part of a urea moiety, and it is unclear what is meant as the metes and bounds of the term “ prodrug” in this instance. The specification gives little guidance and talks about sulfoxide or sulfone derivatives as prodrugs but does not specify even where the sulfoxide or sulfone derivative would be on the molecule. Would it be on the ring or would it be as a counter ion of an acidic nitrogen environment? Could the prodrug include a aziridine type ring that could be opened up and then halogenated to form the ethylene chloro compound ? Could a prodrug be a transition metal complex which releases the metal upon dissolution in the body? The term prodrug is confusing as written (in view of the chemical compound and the specification) as to the metes and bounds of what is being claimed.

Claim 4 recites the limitation of “ isolating effect and responsiveness of the molecule against said cell receptors.” How does one isolate and effect? One can isolate a compound or a mixture. And how does one isolate a responsiveness? The claim is vague and indefinite as to the metes and bounds of what is being claimed.

The examiner notes that claim 4 recites “ protein receptors” in line 1 and then in line 9 and 10 there is a recitation of “various cell receptors” and “ said cell receptors”. The receptors are usually protein receptors however if the various cell receptors are only protein receptors then it would be clearer if the term protein were part of the terminology.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP

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§ 2172.01. The omitted elements are: the claim recites the limit of isolating effect and responsiveness of the molecule against said receptors, however there is no description of what the range of responsiveness is in terms of activity or any other positive response is necessary nor is there any statement about what would be a positive response. The claim is to selectively targeting protein receptors but the claim is unclear as to what elements are to be looked for to tell whether a protein receptor is one that is considered a potential target for the molecule of formula

1. 35 USC 112, second paragraph states in part "one or more claims particularly pointing out and distinctly claiming the subject matter which applicant regards as his invention". The claim is confusing as written and does not particularly point out and distinctly claim the instant invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr J F Vollano whose telephone number is (703) 305-4483. The examiner can normally be reached on Monday to Thursday from 6:30 to 5:00 .

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter , can be reached on (703)308-4532 . The official fax phone number for the organization where this application or proceeding is assigned is (703)308-4556. It should be noted that the examiner cannot immediately work on a fax sent to this number.

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8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

Jean F. Vollano

Primary Examiner

A handwritten signature in black ink, appearing to read "Jean F. Vollano", written in a cursive style.

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December 27, 2001